

**Notice of Allowability**

Application No.

10/009,383

Applicant(s)

GENNARO, MARIA LAURA

Examiner

Rodney P. Swartz, Ph.D.

Art Unit

1645

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 6March2006, interview 1-30-07.
2. ☒ The allowed claim(s) is/are 1-10,35 renumbered 1-11.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some\* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |  |   |
|--|---|
| 1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 5. <input type="checkbox"/> Notice of Informal Patent Application                     |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 6. <input type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date _____ |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),<br>Paper No./Mail Date _____    | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment                   |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance  |
|  | 9. <input type="checkbox"/> Other _____   |

### DETAILED ACTION

1. Applicant's Response to Advisory Action, received 6 March 2006, is acknowledged. Claims 1, 2, 10-26, and 35 have been amended. Claims 27-34 and 36-54 have been canceled.
2. Claims 1-26 and 35 are pending. Claims 19-26 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.
3. Claims 1-18 and 35 are under consideration.

### EXAMINER'S AMENDMENT

4. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee. Authorization for this examiner's amendment was given in a telephone interview with Stuart Macphail, Reg. No. 44,217, on 30 January 2007.

The application has been amended as follows:

#### **IN THE CLAIMS:**

##### **Cancel claims 11-26.**

1. (Currently amended) An isolated DNA molecule ~~comprising~~ consisting of a DNA sequence encoding polypeptide MTBN4.
2. (Currently amended) An isolated DNA molecule ~~comprising~~ consisting of a DNA sequence encoding a segment of polypeptide MTBN4 shorter than full-length polypeptide MTBN4, wherein said segment retains the ~~having *Mycobacterium tuberculosis* specific~~ antigenic and immunogenic properties of MTBN4.

3. (Previously presented) A vector comprising:
  - (a) the DNA molecule of claim 1; and
  - (b) a regulatory sequence operationally linked to said DNA sequence, said regulatory sequence allowing for expression of the polypeptide encoded by said DNA sequence in a cell.
4. (Previously presented) A vector comprising:
  - (a) the DNA molecule of claim 2; and
  - (b) a regulatory sequence operationally linked to said DNA sequence, said regulatory sequence allowing for expression of the polypeptide encoded by said DNA sequence in a cell.
5. (Original) A cell transformed with the vector of claim 3.
6. (Original) A cell transformed with the vector of claim 4.
7. (Original) A composition comprising the vector of claim 3 and a pharmaceutically acceptable diluent or filler.
8. (Original) A composition comprising the vector of claim 4 and a pharmaceutically acceptable diluent or filler.

Art Unit: 1645

9. (Previously presented) A composition comprising at least two DNA sequences, each encoding a polypeptide of the *Mycobacterium tuberculosis* complex that is not a polypeptide encoded by the genome of cells of the Bacille Calmette Guerin (BCG) strain of *Mycobacteria bovis*, said DNA sequences being operationally linked to a regulatory sequence which allows for expression of each said polypeptide in a cell of a vertebrate,

wherein at least one of said at least two DNA sequences is a DNA molecule of claim 1.

10. (Previously presented) A composition comprising at least two DNA sequences, each encoding a functional fragment of a polypeptide of the *Mycobacterium tuberculosis* complex that is not a polypeptide encoded by the genome of cells of the Bacille Calmette Guerin (BCG) strain of *Mycobacteria bovis*, said DNA sequences being operationally linked to a regulatory sequence which allows for expression of each said polypeptide in a cell of a vertebrate,

wherein at least one of said at least DNA sequences is a DNA molecule of claim 2.

11-34. (Cancelled)

35. (Previously presented) The DNA molecule of claim 1, wherein the DNA sequence is *mtbn4*.

36.-54. (Cancelled)

### **Rejection Withdrawn**

5. The rejection of claims 11-18 under 35 U.S.C. 112, first paragraph, scope of enablement for polypeptides other than MTBN4, is moot in light of the cancelation of the claims.

6. The rejection of claims 1-10 and 35 under 35 U.S.C. 112, first paragraph, scope of enablement for polypeptides other than MTBN4, is withdrawn in light of the amendment of the claims.

### **Conclusion**

7. Claims 1-10 and 35 are allowed.

8. The following is an examiner's statement of reasons for allowance: a search of the prior art for DNA encoding a protein named MTBN4 found the name to be unique, and a sequence search of MTBN4 DNA, based upon the instant specification recitation that the sequence for this DNA is SEQ ID NO:12, found that claims drawn to a DNA consisting of a DNA sequence encoding polypeptide MTBN4 or encoding fragments of MTBN4 wherein said fragment retains the antigenic properties of MTBN4, are free of the prior art of record.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

9. U.S. Pat. No. 6,291,190, Behr et al, 18 September 2001, is noted as a reference which compares *M. tuberculosis* and *M. bovis* BCG genomes.

10. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571)


Art Unit: 1645

272-0865. The examiner can normally be reached on Monday through Thursday from 9:00 AM to 7:30 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Jeffrey Siew, can be reached on (571)272-0787.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
RODNEY P. SWARTZ, PH.D.  
PRIMARY EXAMINER  
Art Unit 1645

January 30, 2007